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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/629,340 | 07/28/2003 | Margret Oethinger | PKZ-035CPA2CN2 | 6345 |
| 959 | 7590 | 04/26/2005 | EXAMINER | |
| LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109 | | | LEARY, LOUISE N | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1654 | |
| DATE MAILED: 04/26/2005 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/629,340 | Applicant(s) OETHINGER ET AL | |
| | Examiner Louise N. Leary | Art Unit 1654 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 December 2003 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>12/01</u> . | 6) <input type="checkbox"/> Other: _____ |

1. Claims 25-51 are pending in this application.

Claims 1-24 have been canceled per applicant's request in the amendment filed December 1, 2004.

2. The rejection of claims 1-24 under the statutory type 35 USC 101 double patenting as claiming the same invention as that of claims 1-24 of prior U.S. Patent No. 6,346,391 B1 is moot in view of the cancellation of original claims 1-24 in the amendment filed December 1, 2004.

3. (A) The rejection of claims 1-24 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 6,677,133 is moot in view of the cancellation of original claims 1-24 in the amendment filed December 1, 2004.

(B) The rejection of claims 1-24 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 6,448,006 is moot in view of the cancellation of original claims 1-24 in the amendment filed December 1, 2004.

4. **New Grounds of Rejection:**

(I). Claims 25-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 25, 35, and 45 improperly set forth limitations in parentheses "()" which renders the claims indefinite. It is unclear whether the limitations in the parenthesis "()" are actually intended to be claim limitations.

Correction is required to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(II). The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

(A). Claims 25-51 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,346,391

B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant invention claims a method for screening for compounds that reduce antibiotic resistance in a microbe comprising an AcrAB or AcrAB-like efflux pump which was previously claimed in U. S. Patent No. 6,346,391 B1. Also, both inventions use the compounds identified to treat infection caused by the microbes in subjects. Both inventions claim a method of screening for compounds that inhibit the activity of the AcrAB or AcrAB-like efflux pump. As a result, each method identifies compounds that inherently reduce antibiotic resistance in the microbe. Additionally, both inventions use the same starting materials wherein the microbe is resistant to fluoroquinolones and comprises at least one chromosomal mutation in a gyrase or topoisomerase gene. Further, each invention selectively uses Gram negative bacterium that is contacted with test compounds from a library of test compounds. Thus, both inventions claim identical or closely analogous method steps, starting materials and desired results. Therefore, the invention claimed in U. S. Patent No. 6,346,391 B1 renders the instant invention obvious to one having ordinary skill in this art at the time this invention was made. It is further noted that there is substantial overlap of the subject matter claimed in both inventions.

(B). Claims 25-51 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,677, 133. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant invention claims a method for screening for compounds

that reduce antibiotic resistance in a microbe comprising an AcrAB or AcrAB-like efflux pump which was previously claimed in U. S. Patent No. 6,677,133. Also, both inventions use the compounds identified to treat infection caused by the microbes in subjects. Both inventions claim a method of screening for compounds that inhibit the activity of the AcrAB or AcrAB-like efflux pump. As a result, each method identifies compounds that inherently reduce antibiotic resistance in the microbe. Additionally, both inventions use the same starting materials wherein the microbe is resistant to fluoroquinolones and comprises at least one chromosomal mutation in a gyrase or topoisomerase gene. Further, each invention selectively uses Gram negative bacterium that is contacted with test compounds from a library of test compounds. Thus, both inventions claim identical or closely analogous method steps, starting materials and desired results. Therefore, the invention claimed in U. S. Patent No. 6,677,133 renders the instant invention obvious to one having ordinary skill in this art at the time this invention was made. It is further noted that there is substantial overlap of the subject matter claimed in both inventions.

5. Applicant's arguments filed December 1, 2004 have been fully considered and were found to be persuasive.

(i) At page 8 of the remarks, the examiner agrees with applicant' statements that "Claims 1-22 of the 6,448,006 patent pertain to methods of screening a test compound for ability to induce a multiple antibiotic resistance (Mar) phenotype in a microbe. Induction of a Mar phenotype is assessed by monitoring the expression of a microbial

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gene locus (e.g., marA, soxS, AcrB, etc.) ... In contrast, the claims as presently pending pertain to methods of screening for compounds which reduce antibiotic resistance in microbes comprising at least two of the following traits: i) at least one chromosomal mutation in a gene encoding a antibiotic target that renders the microbe resistant to one or more antibiotics; ii) a second mutations (... The claims further pertain to methods treating infections caused by such microbes. Thus, the compounds, microbes, and responses screened for in 6,448,006 patent are different from those of the presently pending claims. Accordingly, the pending claims are not obvious in light of the claims of the 6,448,006 patent."

6. Applicant's submission of the requirements for the joint research agreement prior art exclusion under 35 U.S.C. 103(c) on December 1, 2004 prompted the new ground(s) of rejection under 37 CFR 1.109(b) presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.02(l)(3). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

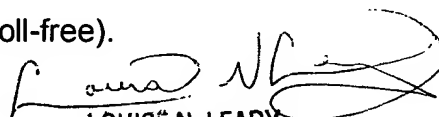
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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise N. Leary whose telephone number is 571-272-0966. The examiner can normally be reached on Monday to Friday from 10 to 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (571) 272-0966. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


LOUISE N. LEARY
PRIMARY EXAMINER

April 21, 2005